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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,270

09/24/2003

Peter A. Altman

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CROCKETT & CROCKETT, P.C.  
26020 ACERO  
SUITE 200  
MISSION VIEJO, CA 92691

EXAMINER

CHENG, JACQUELINE

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

05/12/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/671,270	<b>Applicant(s)</b> ALTMAN ET AL.	
	<b>Examiner</b> JACQUELINE CHENG	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 26, 2009 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed March 26, 2009 have been fully considered but they are not persuasive. The examiner believes that Stevens (US 6,152,141) still stands as Stevens discloses the method as claimed. Stevens injects the therapeutic agent peri-adventitiously by injecting the agent through the coronary wall (into the area that is around the vessel) into the myocardium.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 1, 3, 5, 6, 11, 13, 15, 16, 21, 23, 25, 26, 31, 33, 35, 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Stevens (US 6,152,141).

5. **Claims 21, 25, 26, 31, 35, 36:** Stevens teaches a method of delivery of therapeutic agents to the heart by injecting agent directly into the myocardium by piercing the wall of the coronary artery (col. 8 line 37-40, fig. 9 and 10b). Stevens discloses that the agent can be any type of drug or agent including genes (an anti-restenosis agent comprising gene therapy agents) (col. 2 line 38-48).

6. **Claims 1, 3, 5, 6, 11, 13, 15, 16, 21, 23, 25, 26, 31, 33, 35, 36:** As another embodiment Stevens teaches a method of treating stenosis comprising the steps of implanting a stent within a coronary artery (performing an angioplasty procedure), the stent having needles protruding radially outward to penetrate the coronary artery wall which provide a conduit for delivery of a therapeutic agent into the surrounding myocardium through the blood vessel wall (injecting perivascularly) (col. 10 line 18-24). Stevens discloses that the agent can be any type of drug or agent including genes (an anti-restenosis agent comprising gene therapy agents) (col. 2 line 38-48).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. **Claims 4, 14, 24 and 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens. Although Stevens does not explicitly disclose placing the stent with needles in the coronary vein, it is obvious to one skilled in the art to place the stent where the occlusion has occurred for the purpose of treating the stenosis. If the occlusion occurred in the coronary vein instead of the coronary artery it would be obvious to place the stent in the coronary vein in order to treat the stenosis.

9. **Claims 7, 8, 17, 18, 27, 28, 37, and 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of Nash (US 6,709,427 B1). Stevens discloses the stent has needles to provide a conduit for delivery of the agent into the surrounding myocardium. Stevens also discloses delivering the therapeutic agent in a time released manner. It would therefore be obvious to one skilled in the art to inject into the needles of Stevens a time released agent into the myocardium for the purpose of a slow release of the agent for a prolonged therapeutic benefit. It would be obvious to use any well known time released agent such as disclosed by Nash. Nash discloses agents such as anti-inflammatory agents that are encapsulated in microspheres that degrade over time (col. 30 line 66-col. 31 line 14).

10. **Claims 8-10, 18-20, 28-30, and 38-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of Mixson (US 6,090,728). Stevens discloses that any type of drug or agent can be delivered so it would therefore be obvious to use any well known drug or agent depending on the therapeutic result desired. For anti-angiogenic purposes it would be

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obvious to deliver an anti-angiogenic gene in a carrier vehicle of liposomes, micelles or microspheres such as disclosed by Mixson (col. 5 line 65, col. 6 line 3-5).

11. **Claims 1, 2, 6-8, 11, 12, 16-18, 21, 22, 26-28, 31, 32, and 36-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash in view of Stegmann (US 2002/0122792 A1). Nash discloses a method of delivering agents to a targeted tissue as an adjunctive therapy such as stenting (col. 17 line 19-25) comprising injecting the agent into the myocardium from an endocardial region (col. 19 line 10-14). Nash does not explicitly disclose from where in the endocardium the agent is injected to so therefore it would be obvious to one skilled in the art to inject the agent from anywhere in the endocardium depending on the region that needs to be treated. If Nash was treating a stenosis in the coronary blood vessel it would be obvious to inject the agent (such as a time released anti-inflammatory encapsulated in microspheres, col. 30 line 66- col. 31 line 14) proximate the coronary blood vessel as disclosed by Stegmann (paragraph 0015).

12. **Claim 41 is** rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens further in view of Kunz (US 5,981,568). Stevens does not explicitly disclose a kit comprising the parts of their method. It would be obvious to put the parts needed to perform a method in a kit as well as instructions to perform the method as this is well known in the art to do. For example, Kunz discloses not only a kit to perform a method, but also discloses in particular a kit for inhibiting restenosis comprising a catheter, a dose of therapeutic agent, and instruction means for directing the kit's use. Since the method of Stevens comprises positioning the catheter into the desired

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location (capable of being the perivasular space) and delivering the dose to where the catheter is placed, it would be obvious that the instructions would state this.

### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768